

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA and the  
COMMONWEALTH OF MASSACHUSETTS,

Plaintiffs, ex rel.

LISA WOLLMAN, M.D.,

Plaintiff-Relator,

v.

THE GENERAL HOSPITAL CORPORATION  
(d/b/a the Massachusetts General Hospital), THE  
MASSACHUSETTS GENERAL HOSPITAL'S  
PHYSICIAN'S ORGANIZATION and  
PARTNERS HEALTHCARE SYSTEM, INC.,

Defendants.

Civil Action No. 15-11890-ADB

**DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR  
MOTION FOR SUMMARY JUDGMENT**

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## I. INTRODUCTION

Relator contends that over a period of at least thirteen years (from 2008 to the present) the Defendants—Massachusetts General Hospital, the physicians’ organization that employs most of the hospital’s surgeons, and their parent corporation (collectively, “MGH”)—routinely submitted false and fraudulent claims to the federal and state governments for orthopaedic surgeries. Relator identifies just under 2,000 surgeries which, she contends, resulted in false claims for payment to the government. Relator’s attack focuses on a practice, specifically contemplated and authorized by federal billing guidance, that generally permits surgeons to bill for surgical procedures so long as they are present for the key and critical parts of those procedures—even if physicians-in-training complete the non-critical portions of surgeries. Relator claims that, in violation of federal and state requirements, MGH permitted a small group of orthopaedic surgeons to operate on two patients in separate operating rooms at the same time. She contends that MGH billed government payors for these procedures without obtaining proper consent from patients. She also contends that MGH unlawfully subjected patients to prolonged and medically unnecessary anesthesia during those procedures, and unlawfully left unsupervised residents to perform these surgeries while senior orthopaedic surgeons operated on other patients in other operating rooms.

But discovery has shown that Relator’s claims are without merit—a hyperbolic, tabloid version of the way MGH orthopaedic staff cares for patients. The undisputed facts show that MGH is entitled to judgment on Relator’s claims as a matter of law.

## II. SUMMARY OF ARGUMENT

### A. *Plaintiff’s Claims Concerning Overlapping Surgery and Concurrent Surgery*

At her deposition, Relator acknowledged that academic medical centers commonly permit orthopaedic surgeons to “overlap” cases. *See* Defendants’ Statements of Material Facts (“SOF”)

¶ 79.<sup>1</sup> In overlapping surgical procedures, the patient’s surgeon typically leaves an operating room before the end of a patient’s procedure, and begins participating in a surgery on a second patient while a physician-in-training completes the first patient’s procedure by, for example, closing the surgical wound. *Id.* ¶¶ 77, 79 (“It’s an accepted practice and not uncommon in orthopaedic centers to try to increase efficiency by having small pieces of the beginning and ends of the cases that are overlapping . . . . It is a common practice.”).

Relator’s complaint centers on MGH’s decision to authorize six orthopaedic surgeons—out of approximately 60 orthopaedic surgeons at the hospital—to run two rooms—that is, to schedule two cases to proceed in separate (typically adjoining) operating rooms on the same morning or afternoon. *See* SOF ¶ 8; *see also id.* ¶¶ 7-21 (describing MGH’s orthopaedic surgery department). Relator contends these surgeons (three trauma surgeons, a shoulder surgeon, a spine surgeon, and a sports medicine surgeon) engaged in what she calls “concurrent surgeries” which, she defines as:

surgeries which start at the same time, which are similar in or will go the entire length of time entirely overlapping, and in which key and critical parts, will—could be overlapping in time and would, therefore, need to be artificially staggered in some way. The concurrent surgeries are when the key and critical parts would come at the same time in both cases, potentially.

*Id.* ¶ 81. Relator identified three additional orthopaedic surgeons whom MGH authorized to run two rooms. *Id.* ¶ 80. But she testified that these surgeons’ practices involved “staggering” surgeries for “healthier patients, often in an outpatient setting,” which is “standard” and therefore “not . . . in this complaint.”<sup>2</sup> *Id.*; *see* SOF ¶¶ 75, 76, 78, 82.

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<sup>1</sup> Paragraph references to SOF throughout the brief refer to Defendants’ section of the SOF.

<sup>2</sup> Oddly, however, the list of alleged false claims prepared by Relator’s counsel includes 155 procedures performed by these three surgeons (including government-billed overlapping surgery data

***B. MGH's Practices for Obtaining Patient Consent for Overlapping Surgery Satisfied Legal Requirements and Did Not Result in False Claims.***

Relator contends that MGH submitted false claims because its surgeons did not obtain informed consent from patients to perform overlapping surgeries. Second Amended Complaint, D.E. 89 (“SAC”) ¶¶ 102-114. These claims fail for at least the following three reasons.

- *First*, about fifteen years ago, CMS rejected the approach which Relator now contends applies here. Relator’s purported requirement that overlapping surgery be disclosed is invented. It appears nowhere in the statutes, regulations, or CMS guidance.
- *Second*, the Informed Consent regulations and administrative guidance Relator cites cannot be the basis for a False Claims Act case because they relate to a “Condition of Participation” and not a material condition of payment.
- *Third*, to the extent Relator relies upon CMS guidance to support her claims about informed consent, they must fail because the guidance was issued without the required notice-and-comment process, and thus is not a proper basis for a False Claims Act claim under recent Supreme Court precedent.

***C. Based on Undisputed Facts, Relator's Contention That MGH Filed Claims for Prolonged and Medically Unnecessary Anesthesia Fails as a Matter of Law.***

Relator also claims that “virtually every claim” for overlapping surgery is “inflated” because, according to her, overlapping surgeries led to delays that increased operative times and therefore the time patients spent under anesthesia, which Relator asserts is medically unnecessary. SAC ¶ 101. This sweeping claim must fail for at least three reasons:

- *First*, her theory of prolonged anesthesia being medically unnecessary and improper for billing finds no support in any statute, regulation, or administrative guidance.
- *Second*, Relator’s theory is based on a mistaken understanding of medical necessity, which under Medicare, focuses on whether the procedure itself is necessary, and not whether the procedure was performed in a particular manner, sequence, or timing.
- *Third*, Relator’s theory makes no practical sense under the anesthesia billing rules, which put the anesthesiologist in charge of initiating the critical events that determine anesthesia

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for Drs. Gill (147 cases), DiGiovanni (7 cases), and Theodore (1 case)). SOF ¶ 80; *see also id.* ¶¶ 118, 119.

billing. The anesthesia billing regulations are not, and should not be construed to be, standards governing surgeons' operative speed or efficiency.

***D. Based on Undisputed Facts, Relator's Claim That MGH Filed False Claims When It Billed Medicare for Overlapping Surgeries Fails as a Matter of Law.***

Relator contends that MGH submitted just under 2,000 false claims for orthopaedic surgeries because MGH's surgeons allegedly failed to follow certain federal requirements to bill for overlapping surgery. *See* SAC ¶ 94. Her theory rests on a guideline in the Medicare Claims Processing Manual known as the Teaching Physician Rule that has permitted surgeons at Academic Medical Centers across the country to bill Medicare for overlapping surgeries for decades, so long as certain conditions are met. *Id.* Relator's claims about the Teaching Physician Rule fail for at least three reasons:

- *First*, like the Medicare guidelines on informed consent, the Teaching Physician Rule is sub-regulatory guidance, which under recent Supreme Court precedent cannot be enforced as a substantive legal standard, or support a claim under the False Claims Act, because it did not go through the statutorily required notice-and-comment process.
- *Second*, discovery reveals that MGH developed policies and practices to comply with the billing guidance provided by the Teaching Physician Rule; trained surgeons on the rule, and audited surgeons' compliance with the rule. *See* SOF ¶¶ 22-33, 65-74, 85-104. These actions—and others—undermine Relator's allegation, necessary to prove in a False Claims Act case, that MGH knowingly submitted false claims. SOF ¶¶ 22-33, 85-104.
- *Third*, as a matter of law, Relator's allegations are premised on purported violations of the Teaching Physician Rule that are highly technical and not material. The undisputed facts show that, as a matter of practice, MGH's orthopaedic surgeons went beyond the Teaching Physician Rule's principal requirement: they were not only *present* for the key and critical parts of their surgeries, but performed those key and critical parts themselves.

### **III. STANDARD OF REVIEW**

Summary judgment is appropriate if the pleadings, depositions, answers to interrogatories, and admissions on file, together with any affidavits, show that there is no genuine issue of material fact and that the moving party is entitled to a judgment as a matter of law. Fed. R. Civ. P. 56(a).

#### IV. ARGUMENT

##### A. *Relator's Claims Regarding Invalid Informed Consent Fail as a Matter of Law.*

According to Relator, consent for overlapping orthopaedic surgeries at MGH must have been “invalid,” because “MGH’s written informed consent documents” did not “mention that the surgeon will be involved in another surgery at the same time.” SAC ¶ 7. This purported “requirement” is the Relator’s own invention, and finds no support in any statute, regulation, or sub-regulatory guidance. CMS first issued guidelines on overlapping surgery in 1996 and has modified that guidance on a number of occasions since, but has never required that surgeons make discussion of overlapping surgery part of the consent process. *See* Expert Report of Thomas Gustafson, attached hereto as Exhibit A, (“Gustafson Rep.”) ¶¶ 57-58, 62-71. Indeed, the history of CMS’ guidance on surgical consent forms makes clear that, in 2007, CMS rejected an informed consent policy that tracked closely the approach Relator now advances. *See id.* ¶ 71. Moreover, CMS regulations governing informed consent are part of CMS Conditions of Participation regulations, not conditions of payment, and therefore cannot properly form the basis of a False Claims Act suit. Finally, to the extent that Relator relies on CMS’ sub-regulatory guidance as the basis for her case, the Supreme Court’s recent decision in *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1809 (2019), forecloses Relator’s claim.

##### 1. *Relator's Informed Consent Theory Conflicts with the Regulations and CMS Guidelines, and CMS Rejected It Fifteen Years Ago.*

###### a. The Medicare Regulations Do Not Require Disclosure of Overlapping Surgery.

Medicare’s informed consent regulations do not require surgeons to inform patients about overlapping surgery. The regulations provide simply that a “properly executed informed consent form” be placed in the patient’s chart before surgery, and that patients are informed of their health statuses, are involved in care planning and treatment, and are able to request or refuse treatment,

as part of their right to make informed decisions regarding care. *See* 42 C.F.R. §§ 482.13(b)(2), 482.24(c)(4)(v), 482.51(b)(2).

b. In 2007, CMS Rejected an Approach to Informed Consent that Closely Tracks What Relator Contends is Required.

CMS’s guidance on hospital consent practices—in place since 2007—also refutes Relator’s theory that the billing rules somehow require the specific disclosure about overlapping surgery. Instead, the guidance primarily tracks the regulatory requirements outlined above. It reiterates that an executed consent form must be placed in the patient’s records before a procedure and requires that the form contain certain basic information, such as the name of the hospital, the name of the procedure, the responsible practitioner, the patient’s signature, and the date the form is signed. *See* Gustafson Rep. ¶¶ 67-68, 71. The guidelines also say that the form should include a statement that the practitioner explained the material risks and benefits, but that the determination whether a risk or benefit is material should be based on “the available clinical evidence as informed by the practitioner’s professional judgment.”<sup>3</sup> CMS State Operations Manual (Pub. 100-07), Appendix A (Hospitals), A-0466. (Emphasis added.) The guidelines do not purport to dictate how the practitioner must exercise that professional judgment when discussing procedures with patients.

The history behind these guidelines further refutes Relator’s theory that the rules *mandate* that surgeons make detailed disclosures about what role they and others will play in surgical procedures. As the expert report MGH filed with this motion explains, CMS in 2005 issued guidance requiring consent forms to contain specific, detailed language similar to the detailed disclosures

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<sup>3</sup> The SOM is accessible at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS1201984/>. This manual is sub-regulatory guidance setting out “Interpretive Guidelines” used to instruct surveyors in the field about survey procedures used to ascertain if a hospital is in compliance with the hospital Conditions of Participation. *See* Gustafson Rep. ¶¶ 64, 67.

Relator claims MGH should have made, but quickly backtracked and abandoned the mandate for such detailed disclosures. Gustafson Rep. ¶ 71. The 2005 guidance called for surgical consent forms to include the names of the practitioners performing the “opening and closing” of the surgical field aspects of procedures—aspects of procedures often performed by residents and which Medicare’s regulations specifically permit residents to perform. *See* Gustafson Rep. ¶ 71; SOF ¶ 29; 42 CFR § 415.172(a)(1)(i).

CMS’ 2005 language called for surgical consent forms to include the:

Names of practitioner(s) performing the procedure(s) or important aspects of the procedure(s), as well as the name(s) and specific significant surgical tasks that will be conducted by practitioners other than the primary surgeon/practitioner. (Significant surgical tasks include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues.

\* \* \* \* \*

Furthermore, informed consent would include that the patient is informed as to who will actually perform important parts of the surgical procedures, even when under the primary surgeon’s supervision, the patient must be informed of who these other practitioners are, as well as, what important tasks each will carry out.

*Id.* But in 2007, CMS reversed course and issued its superseding guidance, outlined above, which eliminated the mandate of detailed disclosures, significantly scaling back what CMS calls for from hospital surgical consent forms. *Id.* In place of the 2005 guidance requiring consent forms to disclose, for example, the name of the individuals performing the opening and closing of the surgical field, CMS guidelines currently offer a non-binding illustration of a “well-designed” consent process. SOM at A-0955; Gustafson Rep. ¶¶ 67-68. That illustration—the principal ground that Relator advances for claiming that MGH submitted false claims based on the absence of informed consent, *see* SAC ¶ 65—is now a mere suggestion, not a requirement. *See* Gustafson Rep. ¶¶ 67-68.

Moreover, even this suggestion contains no mention of the disclosure of overlapping surgery. At most, this instruction manual for surveyors suggests, but does not purport to require, that as a part of a “well-designed” consent process, hospital policies may provide for disclosing the roles of residents in particular procedures and address the presence of the lead surgeon. *See* Gustafson Rep. ¶ 67. This clear reference to teaching physician practices—that is, the instruction of residents—omits any mention of overlapping surgery, even though separate CMS guidance on teaching physician practices discusses overlapping surgeries explicitly and at length, allowing physicians and hospitals to bill for them. In any event, CMS confirmed that this suggestion was just that—not a binding requirement for hospitals or physicians. MGH’s alleged failure to comply with this non-mandatory recommendation cannot properly form the basis of a False Claims Act case—let alone one made *knowingly* or *recklessly*, as Relator must prove.<sup>4</sup> *See Infra* Section IV.(C)(2).

2. *The CMS Regulations and Guidance, which Relator Relies Upon, Cannot, as a Matter of Law, be the Basis for a False Claims Act Case.*

a. The Informed Consent Regulations are Conditions of Participation, not Material Conditions of Payment, and So Cannot be the Basis of a False Claims Act Case under Recent Supreme Court Precedent.

As noted above, CMS’s informed consent *regulations* are part of Medicare’s Conditions of Participation. They provide that a “properly executed informed consent form” be placed in the patient’s chart before surgery, and that patients are informed of their health statuses, are involved

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<sup>4</sup> In a similar context, addressing scienter under the Fair Credit Reporting Act, the Supreme Court held that scienter was not present where defendants reading of a statute was not objectively unreasonable. *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 69-70 (2007). The Court found it significant that defendant did not have the benefit of guidance warning it away from the view it took of the statutory language at issue. *Id.* at 70. Here, where there was a complete absence of guidance warranting an alternative approach to informed consent, there was nothing to warn Defendants away from their approach, and scienter is not present as a matter of law.

in care planning and treatment, and are able to request or refuse treatment, as part of their right to make informed decisions regarding care. *See* 42 C.F.R. §§ 482.13(b)(2), 482.24(c)(4)(v), 482.51(b)(2). The fact that they are explicitly Conditions of Participation—and not conditions of payment—is critical here, and ultimately fatal to Relator’s False Claims Act suit.

As the name suggests, hospitals must agree to abide by Conditions of Participation to participate in the Medicare program. *See* Gustafson Rep. ¶ 21. These conditions address a large number of aspects of hospital structure, organization, and procedures, including aspects such as infection control, safety of physical plant, credentialing and organization of medical staff, maintaining medical records, including informed consent. *Id.* The government does not refuse to pay individual claims based on noncompliance with Conditions of Participation, including the informed consent condition. *See* Gustafson Rep. ¶ 25. Rather, after periodic surveys conducted either by CMS or entities such as the Joint Commission on CMS’s behalf, the government may impose corrective-action requirements, in other words, prospective measures, to allow hospitals to reform their practices and return to compliance. *See* Gustafson Rep. ¶ 25. Importantly, during this period of corrective action, in most cases, the hospital *may still bill*, and the government *will still pay*, for the physicians’ services. As one court has explained:

Although Defendants’ alleged non-compliance with Conditions of Participation may lead to prospective corrective action or even termination, Plaintiff has not presented any evidence that Defendants would have been ineligible to receive payment of its Medicare claims during a potential period of non-compliance. In contrast, Defendants have presented ample evidence that even assuming they failed to comply with Conditions of Participation and/or other applicable standards of care, the Government would nevertheless have continued to reimburse their claims at least for a period of time. Thus, Plaintiff has not presented specific facts showing that there is a genuine issue for trial.

*See United States ex rel. Landers v. Baptist Mem’l Health Care Corp.*, 525 F. Supp. 2d 972, 978 (W.D. Tenn. 2007). *See also United States ex rel. Leysock v. Forest Labs, Inc.*, 55 F. Supp. 3d 210,

213-14 (D. Mass. 2014) (relying on *Landers* to rule that FCA liability did not apply when a defendant had certified compliance with all “federal health-care program requirements” but was in fact violating a settlement agreement with the government requiring the submission of annual compliance reports); *United States ex rel. Hartwig v. Medtronic, Inc.*, 2014 U.S. Dist. LEXIS 44475, at \*37-41 (S.D. Miss. Mar. 31, 2014) (holding in the alternative that the informed consent conditions of participation were not conditions of payment that could be the basis for FCA liability).

This point is reinforced by the Supreme Court’s decision in *Universal Health Servs. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989, 2001, 2003 (2016). *Escobar* further limited the kind of legal requirements that could give rise to False Claims Act violations by observing that *even violations of certain express conditions of payment* might not support False Claims Act liability. *See Escobar*, 136 S. Ct. at 1996. *Escobar* focused on the materiality of the condition at issue. *Id.* The plaintiff-relator must show some “evidence that the defendant *knows* that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement.” *Id.* at 2003 (emphasis added).

Here, Relator has no evidence showing that the government has ever rejected a single claim for payment, at MGH or anywhere else, based on deficient consent under the Conditions of Participation. Rather, the undisputed evidence shows that neither CMS, nor the Joint Commission on CMS’s behalf, has ever performed a review of consent practices for overlapping surgery at MGH for billing purposes, including after the Globe published *Clash in the Name of Care* in 2015, after the Senate Finance Committee investigated overlapping surgery, including consent practices, in 2016, or after Relator’s complaint was unsealed in 2017. *See* SOF ¶¶ 122, 147, 161-163.

Indeed, in 2015, the Massachusetts Department of Public Health (“DPH”) reviewed MGH’s informed consent forms in connection with a review of overlapping surgeries and found no violation, observing that MGH’s consent forms “indicated that a team of medical professionals work together to perform the procedure/surgery and their physician or an attending designee will be present for all the critical parts of the procedure.”<sup>5</sup> SOF ¶¶ 134, 223.

Another investigation was conducted in 2016 by the staff of U.S. Senate Finance Committee, which reviewed the overlapping surgery practices at approximately 20 teaching hospitals nationwide, including MGH. SOF ¶¶ 147, 149. The Committee Staff acknowledged that the Medicare Conditions of Participation and corresponding interpretative guidelines are not “specific to concurrent or overlapping operations.” SOF ¶ 228. They also assessed the consent policies of two unnamed hospitals, which did not specifically mention overlapping surgery, but did say that before surgery, the surgeon should discuss his or her involvement with the patient as well as the involvement of other providers. SOF ¶ 232. The Staff observed that these policies, which contained the same information MGH’s policies and consent forms have always included in all their iterations during the relevant period, were “consistent with preexisting CMS guidance.” *See* SOF ¶¶ 180, 232; *see also* SOF ¶¶ 221-239 (describing external group reviews relating to informed consent).

MGH’s policies and forms also, at all relevant times, complied with the plain language of the Medicare regulations and CMS guidance. *See* SOF ¶¶ 164-180. Relator has no evidence that

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<sup>5</sup> Indeed, it was not until 2019 that Massachusetts’ Board of Registration in Medicine (“BORM”) (not CMS) imposed more detailed requirements on disclosures about the identities of physicians participating in surgeries, and even these new regulations did not require disclosure about whether the primary surgeon was participating in overlapping surgery. *See* BORM, Revisions to 234 CMR 2.00 in Effect as of August 9, 2019, *available at* <https://www.mass.gov/news/revisions-to-243-cmr-200-in-effect-as-of-august-9-2019>. Further demonstrating lack of scienter, when BORM imposed these requirements, MGH modified its consent form to comply. *See* SOF ¶¶ 199-200.

MGH medical records lacked properly executed consent forms. Nor can she show that those forms, in any of their iterations, did not contain at the very least the information CMS guidelines recommend, including several elements of the CMS’s non-binding suggestions for “well-designed” consent forms. *See* SOF ¶¶ 181-201.

Because the undisputed facts show that the informed consent Conditions of Participation are not, as a matter of law, material conditions of payment under *Escobar*, the Court should reject Relator’s informed consent claims and grant summary judgment to MGH.

b. The Informed Consent Guidelines Cannot be the Basis for a False Claims Act Violation Because They Were Not Issued with Notice and Comment Procedures.

Moreover, to the extent Relator rests her informed consent claims solely on alleged violations of the State Operations Manual, a Medicare guidance document, those claims must fail for the separate reason that, consistent with recent Supreme Court precedent, an individual cannot be liable under the False Claims Act for alleged violations of Medicare guidance that sets substantive legal standards, but was not issued under the statutorily required notice-and-comment process. *See Allina*, 139 S. Ct. at 1809 (citing 42 U. S. C. § 1395hh(a)(2)). The guidance Relator relies on comes from Appendix A of the State Operations Manual, which is not a regulation issued under the Medicare statute’s notice-and-comment process, but rather is sub-regulatory guidance used to instruct surveyors in the field regarding their periodic reviews to ascertain whether hospitals are in compliance with the Conditions of Participation. *See* Gustafson Rep. ¶¶ 64, 67. This Manual is not a program instruction for payment.

The Supreme Court recently made clear in *Allina* that the enforceability of any “rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under [Medicare]” must be subjected to

public notice and a sixty-day comment period. 139 S. Ct. at 1809 (citing 42 U. S. C. §1395hh(a)(2)). The Court there held that a CMS issuance reducing payments made to hospitals serving low-income patients was invalid because “affected members of the public received no advance warning and no chance to comment first, and because the government has not identified a lawful excuse for neglecting its statutory notice-and-comment obligations.” *Id.* at 1808. Although the Court did not define “substantive legal standard,” it rejected the government’s interpretation that the phrase was meant to distinguish a substantive from an *interpretative* legal standard—*i.e.*, one that merely advises the public of the agency’s construction of the statutes and rules which it administers. *Id.* at 1807, 1811.

Though *Allina* was not a False Claims Act case, its logic applies directly to False Claims Act claims. Thus, under *Allina*, administrative guidance, issued without the notice-and-comment procedures specified in the Medicare Act, cannot be used to establish a false claim. District courts have since fine-tuned the Supreme Court’s holding in cases like this one. For example, in *Polansky v. Exec. Health Res., Inc.*, the plaintiff-relator argued that the defendant submitted hundreds of thousands of false claims by classifying patient admissions as “outpatient” rather than “inpatient.” 422 F. Supp. 3d 916, 918-19 (E.D. Penn. Nov. 5, 2019). According to the plaintiff-relator in that case, CMS defined these terms in guidance manuals using a time-based approach (*i.e.*, if the physician expects the patient to need hospital care for 24 hours or more, the physician should treat the admission as inpatient). *Id.* at 920, 932-33. However, the court held that the CMS manuals could not form the basis of a False Claims Act violation after *Allina* because they established substantive legal standards and were not subject to notice and comment. *Id.* at 931. The court distinguished between policies affecting the right to reimbursement—which are more likely to be substantive

legal standards—and policies not affecting CMS’s authority that were instead simply enforcement instructions. *Id.* at 934-35.

More recently, the Department of Health and Human Services (on whose behalf Relator purports to recover), recognized that *Allina* precludes reliance on Medicare guidance. It published an advisory opinion clarifying that it interprets “substantive legal standard” to mean “any issuance that: 1) defines, in part or in whole, or otherwise announces binding parameters governing, 2) any legal right or obligation relating to the scope of Medicare benefits, payment by Medicare for services, or eligibility of individuals, entities, or organizations to furnish or receive Medicare services or benefits, and 3) sets forth a requirement not otherwise mandated by statute or regulation.” *See* Health & Hum. Servs. Off. of the Gen. Counsel, Advisory Opinion 20-05 on Implementing *Allina*, at 1 (Dec. 3, 2020). Recognizing that HHS sometimes cites non-regulatory CMS publications in its enforcement actions, the advisory opinion provides that where “guidance documents set forth Medicare policies or rules that are not closely tied to statutory or regulatory standards, the government generally cannot use violations of that guidance to inform the basis for any enforcement action, because under *Allina*, it was not validly issued.” *Id.* at 2. “The critical question,” according to the advisory opinion, “is whether the violation of the Medicare rule could be shown absent the guidance document.” *Id.* If it cannot, the guidance establishes a norm and, under *Allina*, is invalid unless issued through notice-and-comment rulemaking. *Id.*

The HHS advisory opinion also accords with Department of Justice policy that has been in place throughout much of this case. Specifically, the Department published a memorandum dated January 25, 2018 (referred to as the “Brand Memorandum”), providing that “[g]uidance documents cannot create binding requirements that do not already exist by statute or regulation” and instructing staff that “the Department may not use its enforcement authority to effectively convert agency

guidance documents into binding rules.”<sup>6</sup> The Department has since incorporated this policy into its Justice Manual. *See* U.S. Dept. of Justice, Justice Manual § 1-20.000 (Limitation on Guidance Documents in Litigation), *available at* <https://www.justice.gov/jm/1-20000-limitation-use-guidance-documents-litigation>. The Justice Manual provides that “civil enforcement actions brought by the Department must be based on violations of applicable legal requirements, not mere non-compliance with guidance documents issued by federal agencies, because guidance documents cannot by themselves create binding requirements that do not already exist by statute or regulation.” *Id.* The Justice Manual is clear that the “Department should not treat a party’s non-compliance with a guidance document as itself a violation of applicable statutes or regulations.” *Id.*

Relator’s claims about informed consent rest primarily on purported requirements drawn from Medicare interpretative guidelines that were informally issued without notice or comment under the Medicare Act. Under *Allina*, the guidelines cannot set substantive legal standards, and under the cases and authority following *Allina*, the guidelines cannot serve as a basis for a False Claims Act suit. Relator’s informed consent claims must therefore fail.

***B. Relator’s Anesthesia Claim Fails as a Matter of Law.***

Relator asserts that “virtually every [MGH] claim” for payment for an overlapping orthopaedic surgery “contains inflated charges for anesthesia services and is a false claim.” SAC ¶ 101. In essence, she argues that any additional anesthesia administered during overlapping surgeries is *per se* “unnecessary,” and therefore, fraudulent. *See id.* Her assertion rests, not on any specific

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<sup>6</sup> *See* U.S. Dept. of Justice, Memorandum for Heads of Civil Litigating Components United States Attorneys, at 2 (Jan. 25, 2018), *available at* <https://www.justice.gov/opa/press-release/file/1028756/download>.

evidence, but on the mistaken premise that overlapping surgeries must be longer than non-overlapping surgeries, so more anesthesia time and anesthetic agent is necessarily required. *See* SAC ¶¶ 96, 100-101. This claim has no basis in the law or Medicare regulations governing anesthesia billing. It fundamentally misunderstands how Medicare evaluates medical necessity. And it ignores the undisputed facts that make Relator's reading of the rules illogical and therefore incorrect.

*1. Relator's Theory Finds No Support in the Statute, Regulations, or Guidance.*

The relevant statute, regulations and Medicare guidance do not support Relator's theory. The Medicare statute excludes from coverage "expenses incurred for items or services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y. This statute says nothing about any particular kind of diagnosis or treatment and, alone, cannot support Relator's theory that supposedly prolonged anesthesia services in overlapping surgeries are *per se* unreasonable or unnecessary. *See id.*

The more precise Medicare regulations also fail to support Relator's theory. Those regulations govern billing for "[a]nesthesia time"—that is, "the time during which an anesthesia practitioner is present with the patient." 42 CFR § 414.46(a)(3). Anesthesia time "starts when the anesthesia practitioner begins to prepare the patient for anesthesia services and ends when the anesthesia practitioner is no longer furnishing anesthesia services to the beneficiary." *Id.* Anesthesiologists generally bill for the continuous time in between. *Id.*

The regulations also provide for an exception to billing for continuous anesthesia time, during so-called "interruption[s] in anesthesia time." *Id.* The anesthesiologist may add time "around an interruption in anesthesia time as long as the anesthesia practitioner is furnishing continuous anesthesia care within the time periods around the interruption." *Id.* Thus, the billing regulations for anesthesia contemplate only two scenarios. Anesthesia may be billed for either the continuous time between preparation and end of service, or, if an interruption occurs, for a longer

period at the anesthesiologists' discretion. *Id.* The regulations do not mention reducing billing time for surgeries that exceed a typical length of time, nor instruct an anesthesiologist to bill for a shorter time at their discretion.<sup>7</sup> *See id.*

The relevant Medicare guidance adds nothing to support Relator's theory. This sub-regulatory guidance merely restates the regulations and says nothing about "excessive" anesthesia. CMS Manual System, Pub 100-04 Medicare Claims Processing (Apr. 14, 2017), Sec. 50, at G (providing that anesthesia time is the "continuous time period" between preparing the patient for anesthesia services and ceasing to furnish anesthesia services and noting the exception for interruptions.).

The Court should reject Relator's invented anesthesia standards that do not appear in any statute, regulations, or Medicare guidance. *See Trenkler v. United States*, 268 F.3d 16, 23 (1st Cir. 2001) (presuming an intentional exclusion when Congress includes something in one part of an Act but omits it from another); *see also Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019) ("The regulation then just means what it means"). Congress and regulators know how to prescribe limitations to billing for particular procedures. Section 1395y in fact contains a long list of specific exclusions from Medicare billing that limit the frequency of specific procedures such as physical examinations, mammograms, and prostate cancer screening tests. *See, e.g.*, 42 U.S.C. § 1395y(a)(1)(F), (G), (H), (K). The statute contains no similar exclusion based on duration of anesthesia. And although CMS has written hundreds of pages of Medicare guidance specifying minute details for

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<sup>7</sup> Moreover, 42 CFR § 482.52 governs the standards that a hospital's anesthesia program must meet for it to participate in Medicare. Generally, such programs must be administered by a qualified person, be well organized and proportional to institutional needs, and must keep adequate records. Nothing in these regulations addresses duration or quantity of anesthesia services.

billing for services, nowhere does the guidance mention Relator’s concept of prolonged anesthesia, including in the sections on anesthesia (and concurrent anesthesia) or overlapping surgeries.<sup>8</sup>

2. *Relator’s Theory Is Not Supported by the Concept of Medical Necessity.*

Relator’s claim also finds no support in the general concept of reasonable and necessary medical services. Relator does not allege that any patients should have undergone less intrusive anesthesia, (*e.g.*, local anesthesia rather than general). She focuses instead on incremental time patients allegedly spent under anesthesia beyond what she believes was reasonable or necessary for particular orthopaedic surgeries.

Although CMS has no regulatory criteria for what it considers reasonable or necessary medical services, when CMS pays for services, it generally does not look at parts of procedures to determine whether each part is delivered in a particular manner, sequence, or timing. Gustafson Rep. ¶¶ 94-95. For example, CMS has established payment rates for “bundles” of care for certain treatments, such as osteopathic surgery, or bundled rates for all inpatient facility services for particular diagnoses. Gustafson Rep. ¶ 95. The bundled rates control expenses *without* mirroring the program in physicians’ medical decisions regarding how to deliver care to patients or use hospital resources. *Id.*

Yet Relator’s anesthesia theory would have Medicare doing what the statute prohibits—looking over the anesthesiologist’s shoulder, involving itself in her medical decisions when to start anesthesia services and stop them, when to put a patient under general anesthesia, and how much anesthetic agent to use. *See* 42 U.S.C. § 1395 (Medicare regulations are not intended to “authorize

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<sup>8</sup> In fact, the guidance mentions reasonable and necessary anesthesia services in other contexts but not with respect to calculating anesthesia time. *Compare* CMS Manual System, Pub 100-04 Medicare Claims Processing (Apr. 14, 2017), Sec. 50, at F *with* Sec. 50, at G.

any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided.”). Because Medicare billing is neither equipped nor designed to participate in the minute-by-minute medical judgments involved in providing anesthesia, Relator’s theory of prolonged anesthesia for overlapping surgeries must fail.

3. *Relator’s Theory Leads to an Untenable Interpretation of the Regulations Governing Anesthesia Billing.*

The Medicare regulations for billing anesthesia could not, as a matter of law, require what Relator suggests because those requirements would lead to absurd and untenable outcomes.

First, the anesthesiologist, not the surgeon, is responsible for anesthesia billing. SOF ¶ 245. Although surgery is a team effort in which all members, surgeons and anesthesiologists alike, coordinate regarding how to proceed with surgery, it is undisputed that the anesthesiologist controls when to administer anesthetic agents and when to induce a patient, that is, to put the patient under general anesthesia. *See id.* The surgeon cannot force the anesthesiologist to induce, as Relator, an anesthesiologist who worked for years with MGH’s orthopaedic surgeons, has testified: “I, as a physician, can’t be forced to induce a patient that I don’t want to induce for anesthesia.” *Id.* ¶¶ 245, 249. Only anesthesiologists, like Relator, decide when to start and stop anesthesia time, and how much time to bill. *Id.* If an anesthesiologist believes that a patient may wait unnecessarily under general anesthesia, she may decide not to delay the administration of anesthesia until she is certain a procedure is about to begin. *Id.* The choice is hers, not the surgeon’s. *Id.* Indeed, Relator testified that, while at MGH, she made the choice not to induce “many times for many reasons.” *Id.* ¶ 249.

Second, Relator’s theory runs counter to the important Medicare policy goal of training surgical residents. Teaching new physicians is a principal goal of the Medicare program, one that is supported by significant, congressionally appropriated funds. *See Gustafson Rep.* ¶¶ 17, 96. Yet

it is undisputed that surgeries in which residents participate generally take longer because residents are receiving instruction and perform surgical tasks slower than more senior physicians. Gustafson Rep. ¶ 96; SOF ¶ 248. That extra time means extra anesthesia. Thus, accepting Relator's theory would mean that, by helping train the next generations of physicians, Medicare is also subsidizing medically unnecessary anesthesia in surgeries where residents are learning to practice medicine.

Third, it is undisputed that surgery time is affected by myriad factors. As Relator has acknowledged, some surgeons take longer than others to perform the same surgeries, though the slower surgeon is no less competent. SOF ¶ 248. Other surgeons may have a smaller staff or fewer resources. *Id.* Equipment may not be readily available. *Id.* Certain staff may take longer to set up and prepare operating rooms. *Id.* The same surgery for one patient may take longer for another because of the other's advanced age or poor health condition. *Id.* Relator's theory, in essence, would set a reasonable and necessary time for surgical procedures across the board, regardless of these many factors. But that cannot be how Medicare billing functions. Medicare is not watching over surgeons in the operating room with a stopwatch. The Medicare program is not equipped to determine in any given procedure whether "extra" surgery time was unnecessary because it was due to overlap or some other supposedly acceptable reason.

Relator's theory is inconsistent with the Medicare statute's admonition that Medicare regulations should not direct medical practice. *See* 42 U.S.C. 1395. It is inconsistent with the anesthesia billing regulations, which put the anesthesiologist in charge of anesthesia billing and permit upward adjustments for "interruptions" but do not contemplate downward write-offs for supposedly unnecessary anesthesia time. *See* 42 CFR § 414.46(a)(3). And it is inconsistent with accepted medical practice, which focuses on patients' individual needs, rather than treating all patients alike

by allowing surgeons a fixed, “reasonable” time to finish their surgeries.<sup>9</sup> *See*; Gustafson Rep. ¶ 95-96.

The Court should therefore reject Relator’s theory which would lead to an untenable interpretation of the requirements for anesthesia billing, and grant summary judgment to MGH on Relator’s anesthesia claims.

***C. Relator’s Teaching Physician Rule Claim Fails as a Matter of Law.***

Relator also contends that every government-billed overlapping orthopaedic surgery performed at MGH was a false claim because MGH failed to follow CMS’ guidance that *expressly allows* teaching surgeons to bill for their role in overlapping surgeries. *See* SAC ¶ 94. Specifically, Relator alleges that MGH submitted bills to the government that did not conform to several paragraphs of guidance at Section 100.1.2(A)(2) of Chapter 12 of the Medicare Claims Processing Manual (the “Claims Processing Manual”). *See id.* According to Relator, MGH’s alleged failure to follow this guidance means that it was not entitled to reimbursement from a government payer for just under 2,000 orthopaedic surgeries performed between 2008 and present, and that its submission of bills for these surgeries constitutes a false claim in violation of the False Claims Act. *See* SOF ¶ 84. Relator’s argument fails as a matter of law.

***1. Relator Has Failed to Establish That MGH Violated Any Applicable Regulation, and the Guidance Documents Relator Relies on Specifically Authorize Overlapping Surgery.***

Although Relator’s Teaching Rule theory is primarily premised on violations of the Claims Processing Manual, discussed below, it implicates two key regulations: 42 CFR § 415.170 and

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<sup>9</sup> Relator’s anesthesia theory fails for the additional reason that, as a matter of law, Defendants cannot have acted with scienter where there was no guidance from CMS warning it away from the approach it took. *See Safeco Ins. Co. of Am.*, 551 U.S. at 69-70.

§ 415.172. These regulations address the conditions for payment for physician services in a teaching setting and were intended to prevent Medicare from paying twice for the same procedure. *See* Gustafson Rep. ¶¶ 35, 36. Since Medicare pays for resident involvement in surgical cases through regular GME payments, CMS specified that teaching physicians may bill for a case involving a resident only if the teaching physician has meaningful participation in the case. *See* Gustafson Rep. ¶ 18-19.

Section 415.170 provides that Services meeting the conditions for payment in § 415.102(a)<sup>10</sup> furnished in teaching settings<sup>11</sup> are payable under the physician fee schedule if—(a) “The services are personally furnished by a physician who is not a resident”; or (b) “The services are furnished by a resident in the presence of a teaching physician except as provided in § 415.172.” Section 415.172, in turn, establishes the “[g]eneral rule” that “[i]f a resident participates in a service furnished in a teaching setting, physician fee schedule payment is made only if a teaching physician is present during the key portion of any service or procedure for which payment is sought.” *Id.* § 415.172(a). As it relates to surgical procedures, this means “the teaching physician must be present during all critical portions of the procedure and immediately available to furnish services during the entire service or procedure.” *Id.* § 415.172(a)(1). The regulations do not define “immediately available,” but they do clarify that the teaching physician does *not* need to be present during the opening or closing of the surgical site to bill Medicare for the surgery.

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<sup>10</sup> Services are payable under 42 CFR §415.102(a) if they: (a) are personally furnished by a physician, (b) ordinarily require performance by a physician, and (c) contributed directly to the diagnosis or treatment of a beneficiary.

<sup>11</sup> “Teaching setting means any provider, hospital-based provider, or nonprovider settings in which Medicare payment for the services of residents is made under the direct GME payment provisions of 413.75 through 413.83....” 42 CFR §415.152.

42 CFR § 415.172(a)(1)(i). Section 415.172 also imposes a record-keeping obligation: “the medical records must document that the teaching physician was present at the time the service . . . is furnished.”<sup>12</sup> *Id.* § 415.172(b); *see also* SOF ¶¶ 40-49 (describing MGH surgical records).

The undisputed facts show that MGH has had policies and procedures in place to ensure compliance with these regulations since at least 1999. SOF ¶¶ 49, 85-104. Specifically, surgeons at MGH have been required since that time to include an attestation of surgical presence in the operative report for every surgery. *See id.* ¶¶ 49, 85. MGH has instructed surgeons to attest that they were either present for the entire case, or present for the key portions of the case and immediately available during the entire case. *Id.* MGH policy requires surgeons to be present for all critical portions of a surgery and to document their presence in the medical record, and MGH policy prevents a bill from being submitted when these conditions are not met. *Id.* ¶ 85; *see also id.* ¶¶ 85-104. Accordingly, virtually every medical record at issue in this case describes the facts of the surgery in extraordinary detail, and the surgeon’s attestation of presence certifies his or her presence during, at least, the key and critical portions of the surgery. *See id.* ¶¶ 48-49.

The language of these attestations often varied, surgeon-to-surgeon, but each attestation included either a statement that the surgeon was present for the entire procedure or that the surgeon was present for the key or critical parts of the procedure. *See id.* ¶¶ 85, 87, 89, 97. Moreover, as

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<sup>12</sup> Relator also alleges violations of Massachusetts regulations governing the billing of overlapping surgeries. Those regulations also require that the teaching surgeon be immediately available for non-critical elements of a surgery billed to MassHealth, but they make clear what is implicit in the federal regulations: that a surgeon’s involvement in the non-critical elements of a second procedure does not mean that the surgeon is *not* immediately available to return to the first procedure. Specifically, the Massachusetts regulations provide that the surgeon “must not be involved in another procedure from which he or she cannot return.” 130 CMR 450.275(D)(4). The regulations further provide that surgical presence “may be demonstrated by the notes in the medical records made by the physician.” 42 CFR § 415.172(b).

noted, the operative report contains a detailed description of the procedure which often provides additional details concerning the surgeon's presence. *See id.* ¶ 48. Accordingly, the medical records for each of these procedures show that the surgeons were sufficiently involved in the procedure to bill Medicare for their professional services. MGH complied with the applicable regulations.

The fact that these surgeries overlapped does not change the analysis. A plain reading of the regulations supports billing for overlapping surgeries (just like any other surgery) as long as the teaching surgeons meaningfully contributed to the care of each patient and appropriately memorialized their involvement in the medical record. Contrary to the allegation in Relator's complaint, there is no evidence that MGH billed the government for overlapping surgeries in which the billing surgeon was not present for the key or critical portions of the surgery. To the contrary, MGH's policy requires attending physicians (including teaching physicians) always to be present during the key or critical parts of their surgeries. *Id.* ¶ 37. In sum, the undisputed facts show that MGH complied with federal regulations regarding teaching surgeon billing.

Unable to prove a violation of any applicable law or regulation, Relator reaches down to the realm of sub-regulatory guidance. She contends that teaching surgeons at MGH submitted professional bills in cases in which they did not follow all of the instructions in Section 100.1.2(A)(2) of Chapter 12 of the Claims Processing Manual. SAC ¶ 94. That subsection incorporates the same fiscally-motivated requirements of 42 CFR § 415.172(a)(1)—the surgeon must be present for critical portions, and immediately available when not present—but it goes beyond the scope of the regulations in several respects relevant to this case.

Mirroring the regulatory requirements, Section 100.1.2(A)(2) provides that “[i]n order to bill Medicare for two overlapping surgeries, the teaching surgeon must be present during the critical or key portions of both operations.” Similarly, the Claims Processing Manual guidance underscores the need to keep a record of the surgeon’s involvement in the surgery, requiring the teaching surgeon to “personally document in the medical record that he/she was physically present during the critical or key portion(s) of both procedures.”<sup>13</sup> In these respects, the Manual is largely consistent with the regulations, and as discussed above, the undisputed evidence shows that MGH complied with the regulatory requirements.

But the Manual provision goes on to add some elements not present in the regulations, including:

- “When all of the key portions of the initial procedure have been completed, the teaching surgeon may begin to become involved in a second procedure.”
- “When a teaching physician is not present during non-critical or non-key portions of the procedure and is participating in another surgical procedure, he/she must arrange for another qualified surgeon to immediately assist the resident in the other case should the need arise.”
- “During non-critical or non-key portions of the surgery, if the teaching surgeon is not physically present, he/she must be immediately available to return to the procedure, i.e., he/she cannot be performing another procedure.”

Medicare Claims Processing Manual, 100.1.2 Surgical Procedures.

Each one of these provisions purports to establish a substantive legal standard not found in the regulations and that were not subject to the Medicare Act’s notice-and-comment process. Thus, similar to the informed consent interpretative guidelines discussed above, these extra-regulatory

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<sup>13</sup> This language further underscores why inaccuracies regarding a surgeon’s statement that s/he was present for the “entire case” are immaterial. The real focus was on being present for the key or critical parts, and at MGH attending physicians not only were present but were scrubbed in for those portions as a matter of policy.

requirements of the Teaching Physician Rule cannot serve as a basis for a False Claims Act claim under *Allina* and the cases and authorities following that Supreme Court decision. *See* Part IV.A.2b, *supra*. Relator’s argument that MGH failed to adhere to purported requirements found only in CMS guidance regarding billing for overlapping surgeries runs afoul of Supreme Court precedent, and thus fails as a matter of law.

2. *The Undisputed Facts Show that MGH Did Not Act with Scienter.*

Relator’s Teaching Physician Rule argument fails for yet another reason: the undisputed evidence shows that MGH acted in good faith and sought to comply with all applicable CMS guidance. Thus, Relator cannot show what she must—that MGH *knowingly* presented a false claim for payment. *See* 31 U.S.C. §§ 3729(a)(1)(A), 3729(a)(1)(B). The statute defines “knowing” and “knowingly” as having “actual knowledge” of information or acting in “deliberate ignorance” or “reckless disregard” of the truth or falsity of information. 31 U.S.C. § 3729(b)(1).

Here, the undisputed facts show that MGH developed policies aimed at complying with CMS’ guidance regarding billing for overlapping surgery, trained surgical staff regarding those policies, and sought to ensure compliance through routine monitoring, among many other good-faith efforts to comply with CMS guidance regarding teaching physician billing. *See* SOF ¶¶ 85-104. These efforts included, but were not limited to:

- Implementing a policy (effective throughout the relevant time period) requiring surgeons to be present for the key or critical parts of a surgery in order to bill for it and requiring surgeons to include an attestation certifying that they were present for the key or critical parts. *Id.* ¶ 85.
- Implementing a policy (effective throughout the relevant time period) governing the supervision of trainees and requiring that “even where actual presence is not deemed necessary, an attending shall be readily available to provide consultation and support.” *Id.* ¶ 86.
- Issuing a memorandum to all MGH surgical staff in February 2002 reminding recipients of their obligation to comply with Medicare and Medicaid rules, in particular with respect

to overlapping cases: “If you perform concurrent procedures and the key portion of either case overlaps with any portion of the other case, you must designate a second surgeon to meet the immediate availability requirement in order to bill. This second surgeon must be a staff surgeon who is not engaged in another procedure or who himself must be immediately available for any other procedure at that time. Please note that the determination of what constitutes the key portion of a surgical procedure is made at the discretion of the attending surgeon.” *Id.* ¶ 87.

- Issuing an email memorandum in November 2005 reminding surgeons of MGH’s “Presence Statement Guidelines When Running Two Rooms,” including that: (1) “A surgeon who leaves case # 1 to become involved in the key portions of case # 2 must designate a second staff surgeon to meet the immediate availability requirement;” (2) “For surgeons who work with fellows who are approved for billing all payers (Arthroplasty, Shoulder, Pedi, Trauma, Spine, Oncology) the immediate availability requirement **can be** met by including a statement of the fellow’s presence throughout the case;” and (3) “Those surgeons whose fellows cannot bill all payers (Sports & Hand or if the fellow is not present during the case), must designate a surgeon who is immediately available.” *Id.* ¶¶ 88-90.
- Implementing a formal two-room policy in 2012: “Criteria for Concurrent Staffing of Two Operating Rooms” (the “Two-Room Policy”). *Id.* ¶¶ 93-94.
- Conducting a two-room “Boot Camp” training session to educate surgeons about the Two-Room Policy and providing the Boot Camp training to additional surgeons who were granted two room privileges after 2012, including Drs. Heng, Provencher, and DiGiovanni. *Id.* ¶¶ 95-98.
- Requiring Orthopaedic services to define the key elements of common surgeries (even though CMS leaves the decision of what constitutes a key element to the discretion of the attending surgeon). *See id.* ¶ 39.
- Encouraging services to implement their own supplemental policies and procedures regarding overlapping surgery, as the Shoulder Service did. *Id.* ¶¶ 99-100.
- Providing training regarding the Two-Room Policy to members of the nursing and anesthesia teams, as well as to surgical fellows. *Id.* ¶ 101.
- Amending the Two-Room Policy in 2016 to require a back-up surgeon any time the attending surgeon expected to be involved in an overlapping case (even if the overlap was limited to non-critical portions). *Id.* ¶ 102.

- Conducting additional training on the amended Two-Room Policy. *Id.* ¶ 103.
- Amending the Two-Room Policy again in 2019. *Id.* ¶ 104.
- Monitoring overlapping surgeries and compliance with the Two-Room Policy from at least 2008 to the present, including since 2016 on a quarterly basis and currently on a monthly basis. *Id.* ¶¶ 66-74; *see also id.* ¶¶ 50-64 (describing the billing process).
- Implementing policies of informed consent in both hospital-wide consent policies and in the two-room policies themselves that the Senate Finance Committee recognized as being consistent with Medicare rules. *Id.* ¶¶ 165-220, 238.

Even assuming that Relator's reliance on sub-regulatory guidance is not fatal to her claim, which MGH maintains it is, MGH's extensive efforts to comply with CMS guidance demonstrate that MGH did not act with the requisite scienter and, therefore, the Court should enter summary judgment in MGH's favor.

3. *The Undisputed Facts Show That Any Alleged Violation Was Not Material.*

Although the Court need not reach this issue for the reasons discussed above, any alleged violation of the Teaching Physician Rule is not material. The materiality standard in False Claims Act cases is rigorous and demanding; materiality "cannot be found where noncompliance is minor or insubstantial," and an alleged misrepresentation cannot be deemed material solely because a defendant failed to comply with a designated condition of payment or because the government would have the opportunity to decline to pay if it knew of the defendant's noncompliance. *Escobar*, 136 S. Ct. at 2003. The undisputed facts show that Defendant did not knowingly violate a requirement that they knew was material to the Government's payment decision, *id.* at 1996, and therefore summary judgment should enter in MGH's favor.

The purpose of CMS' teaching physician guidance is to establish when it is appropriate to make Medicare Part B payment to teaching physicians who oversee the services of interns and residents. *See Gustafson Rep.* ¶¶ 33-36. CMS has stated that payment is appropriate so long as the

teaching physician is meaningfully involved in the case, *i.e.*, present for the key or critical portions of the surgery. *Id.* Here, the undisputed facts show that MGH had a policy of requiring surgeons to scrub in for the critical parts of surgery and that surgeons followed that policy. SOF ¶¶ 37, 94. Thus, the purpose of the guidance was met: MGH orthopaedic surgeons were *not* submitting bills in cases performed by residents and in which they had no meaningful involvement.

Thus, Relator’s claim turns on alleged technical violations. For example, Relator contends that MGH failed to adhere strictly to the requirement in the Claims Processing Manual—but not the regulations—specifying that a surgeon must complete all the critical parts of the first procedure before moving to a second procedure. *See* SAC ¶ 45. For example, where a surgeon starts and finishes a shorter procedure within the procedure time of a longer procedure, Relator alleges a violation because she assumes that the surgeon must have returned to the longer procedure to complete more critical parts. Any instances of a surgeon moving back-and-forth between rooms is not material where the surgeon was otherwise meaningfully involved in, that is, present for the critical portions of, the billed case. Similarly, Relator points to obvious errors in surgeons’ attestations as proof of fraud—*i.e.*, where a surgeon attests to being present for the “entire procedure” in two overlapping cases. *See* SAC ¶¶ 115-16. But once again, any errors in that regard are not material where it is otherwise clear from the evidence that the teaching surgeon was present for the critical portions of the surgery. Because CMS bases its payment decision on the surgeon’s presence during critical portions—*not presence during the entire procedure*<sup>14</sup>—attestations erroneously stating that the surgeon was present for the entire procedure are not material.

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<sup>14</sup> Indeed, CMS has stated that it “proposed the concept of the key portion of a service or procedure to provide flexibility and to avoid requiring the presence of the teaching physician for the duration of every service or procedure billed in his or her name.” Gustafson Rep. ¶ 38.

Moreover, MGH's overlapping surgical practices have been subjected to incredible scrutiny by government regulators and the press since at least 2012, and despite that scrutiny, CMS has taken no steps to audit or question MGH's billing of overlapping surgeries. SOF ¶¶ 121-161. This scrutiny was not the result of mere routine reviews but rather pointed allegations by Relator and others questioning MGH's overlapping surgery practices. SAC ¶¶ 118-135. Indeed, the Board of Registration in Medicine, the Massachusetts Department of Public Health, and the Joint Commission all looked into MGH's overlapping surgery practices and declined to take any action. SOF ¶¶ 121-145. The Senate Finance Committee staff also investigated overlapping surgical practices at teaching hospitals and, in 2016, reported that, up to that point, CMS had not "taken any steps to determine whether the existing billing requirements applicable to teaching physicians in hospitals are or are not being followed despite a history of problems in this area." *Id.* ¶¶ 147-157. Since 2016, neither CMS nor Congress has taken any further action with respect to billing for overlapping surgery, further demonstrating the lack of materiality. *See Escobar*, 136 S. Ct. at 2003-04 ("[I]f the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.").

## II. CONCLUSION

Accordingly, for the foregoing reasons, MGH's motion for summary judgment should be granted.

Dated: July 15, 2021

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**CERTIFICATE OF SERVICE**

I hereby certify that this document was filed through the ECF system on July 15, 2021, and will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF), and paper copies will be sent to those indicated as unregistered participants.

/s/Aaron F. Lang